NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS DEUTSCHLAND GMBH, AVENTIS PHARMA S.A., ABBOTT GMBH & CO. KG and ABBOTT LABORATORIES Plaintiff, v. GLENMARK PHARMACEUTICALS INC., USA and GLENMARK PHARMACEUTICALS LTD, Defendants.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 07-CV-5855 (DMC-JAD)

DENNIS M. CAVANAUGH, U.S.D.J.

This matter comes before the Court upon motions by Defendants Glenmark Pharmaceuticals, Inc., USA and Glenmark Pharmaceuticals, Ltd. (collectively, "Defendants") for judgment as a matter of law that (1) Abbott Laboratories ("Abbott Laboratories") and Abbott Laboratories, Inc. ("ALI") (collectively, "Abbott Plaintiffs") lack standing, (2) that Abbott Plaintiffs are not entitled to lost profits, (3) that U.S. Patent No. 5,721,244 (the "'244 patent") is invalid for obviousness, and (4) that the '244 patent is invalid for obviousness type double patenting. Plaintiffs moved for a permanent injunction and accounting for supplemental damages. Pursuant to Federal Rule of Civil Procedure 78, no oral argument was heard. After considering the submissions of all parties, it is the decision of this Court for the reasons herein expressed that Defendants' motions for judgment as a matter of law are **denied**, and the Plaintiffs' motion for permanent injunction and supplemental damages is

granted.

I. BACKGROUND

As the Court has issued previous opinions in this case and writes solely for the parties, prior familiarity with the underlying factual and procedural history of this matter will be assumed. In short, this case concerns U.S. Patent No. 5,721,244 (the "'244 patent"), titled "Combination of Angiotensin-Converting Enzyme Inhibitors with Calcium Antagonists as well as their Use in Drugs[,]" issued on February 24, 1998, with a filing date of June 7, 1995 and a foreign application priority date of October 2, 1986. Claim 3 of the '244 patent, the only Claim at issue here, discloses and claims a "pharmaceutical composition" used to treat hypertension. The pharmaceutical composition contains an angiotensin-converting enzyme inhibitor ("ACE inhibitor") having certain bicyclic or tricyclic ring systems and a calcium antagonist (also known as a calcium channel blocker or "CCB") in "amounts effective for treating hypertension." The parties agree that Claim 3 can be expressed as follows:

> A pharmaceutical composition comprising:
> (a) an angiotensin-converting enzyme inhibitor (ACE inhibitor) [which is] trandolapril or quinapril, or a physiologically salt thereof, and
> (b) a calcium antagonist or a physiologically salt thereof;
> wherein said ACE inhibitor and said calcium antagonist are present in said composition in amounts effective for treating hypertension;
> and with the proviso that when said calcium antagonist is ... felodipine, said angiotensin coverting enzyme inhibitor is not ... trandolapril.

Plaintiffs also obtained United States Patent 5,098,910 (the "'910 patent") on March 24, 1992 with a filing date of May 30, 1989 and a foreign application priority date of October 2, 1986. The '910 patent indicates that the "present invention relates to a combination of angiotensin-converting enzyme inhibitors (ACE inhibitors) with calcium antagonists as well as

their use in drugs, especially in hypotensive drugs." The '910 patent claims a pharmaceutical composition comprising of ramipril, an ACE inhibitor, and a calcium antagonist.

Abbott Laboratories is the owner of the New Drug Application ("NDA") No. 20-591. Pursuant to the NDA approval, Abbott Laboratories, through ALI, sells drug products containing the trandolapril/verapamil hydrochloride combination in the United States under the trademark Tarka®. The '244 patent is listed in FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluation" ("Orange Book") as being applicable to Abbott Laboratories' aforementioned NDA for its Tarka® tablets.

On July 24, 2007, Glenmark filed an Abbreviated New Drug Application ("ANDA") No. 79-135 with the FDA for approval to market a generic version of the drug Tarka®. On October 24, 2007, Glenmark notified Plaintiffs that it had made a "Paragraph IV"certification asserting that the '244 patent is invalid. On December 7, 2007, consistent with the provisions of the Hatch-Waxman Act, Plaintiffs initiated suit before this Court against Defendants for patent infringement.

On January 4-14, 2011, a jury trial was held to determine the validity of the '244 patent and the liability, if any, of the Defendants. The jury returned a verdict in favor of Plaintiffs on all counts. Specifically, the jury found that the '244 patent was not obvious and that Plaintiffs were entitled to damages for lost profits and price erosion. The jury also found that the '244 patent was not invalid based on obviousness type double patenting; however, as to this question the jury was advisory only.

Defendants moved for judgment as a matter of law that Abbott Laboratories and ALI lacked standing, that Abbott Plaintiffs are not entitled to damages for lost profits, and that the

'244 patent is invalid for obviousness.[1] Both parties moved for judgment as a matter of law regarding obviousness type double patenting. The Court reserved decision until after the jury rendered its verdict. Following the trial, both parties submitted briefs in support of their motions, findings of fact and conclusions of law with regard to obviousness type double patenting, and Plaintiffs moved for a permanent injunction. At the direction of the Court, the parties subsequently submitted supplemental briefs regarding the permanent injunction. The Court writes now to address these motions.

II. MOTIONS FOR JUDGMENT AS A MATTER OF LAW

A. LEGAL STANDARD

Judgment as a matter of law is appropriate when "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." FED. R. CIV. P. 50(a).

Patents are presumed to be valid. 35 U.S.C. § 282 (1994). Thus, "the burden is on an accused infringer to show by clear and convincing evidence facts supporting the conclusion that the patent is invalid." Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1065 (Fed. Cir. 1998). Accordingly, judgment as a matter of law may be granted in favor of a party bearing the burden of proof "*only* where (1) the movant has established [its] case by evidence that the jury would not be at liberty to disbelieve *and* (2) the only reasonable conclusion is in [the movant's] favor." Id. (internal citations omitted) (emphasis added).

B. STANDING

[1]Plaintiffs also moved for judgment as a matter of law that they are entitled to lost profits damages and that the '244 patent is not obvious. Since the jury returned a verdict in favor of Plaintiffs on these issues, Plaintiffs motions are moot.

Defendants move for judgment as a matter of law that Abbott Laboratories and ALI ("Abbott Plaintiffs") lack standing to sue for infringement of the '244 patent. Prior to trial, Defendants likewise moved to dismiss the Abbott Plaintiffs for lack of standing. This Court denied Defendants' motion. In arguing they are entitled to judgment as a matter of law, Defendants rely on the briefs submitted in support of their prior motions.

In its earlier Opinion addressing the issue of standing, this Court found that Abbott Laboratories and ALI were exclusive licensees of the '244 patent and therefore had standing to sue for infringement. This finding is supported by the evidence that was presented at trial. Accordingly, Defendants' motion is **denied**.

C. LOST PROFITS

Defendants move for judgment as a matter of law that the Abbott Plaintiffs are not entitled to lost profits damages. Defendants previously moved for summary judgment on this issue, and rely on those briefs in support of the motion for judgment as a matter of law.

To the extent that Defendants' argument is based on the payment between co-Plaintiffs Sanofi Aventis and Abbott, this Court has already determined that this payment cannot be used to offset lost profits based on the collateral source rule and in that regard this argument, once again, fails.

The award of damages for patent infringement is governed by 35 U.S.C. § 284, which provides "[u]pon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." 35 U.S.C. § 284. "There are two methods by which damages may be calculated." Hanson v. Alpine Valley

Ski Area, Inc., 718 F.2d 1075, 1078 (Fed. Cir. 1983). "If the record permits the determination of actual damages, namely, the profits the patentee lost from the infringement, that determination accurately measures the patentee's loss." Id. However, "[i]f actual damages cannot be ascertained, then a reasonable royalty must be determined." Id.; see also Micro Chemical, Inc. v. Lextron, Inc., 318 F.3d 1119, 1125 (Fed. Cir. 2003) ("This court must vacate the district court's reasonable royalty calculation to the extent that [Plaintiff] can show entitlement to lost profit damages.").

"Lost profits [are proved] from lost sales, . . .that 'but for' the infringement, [the plaintiff] would have made the sales." *American Seating Co. v. USSC Group, Inc.*, 514 F.3d 1262, 1269 (Fed. Cir. 2008); see also Micro Chemical, 318 F.3d at 1125 ("To recover lost profits a patentee must show that "but for" infringement it reasonably would have made the additional profits enjoyed by the infringer."). Lost profits "requires a showing of (1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) manufacturing and marketing capability to exploit the demand, and (4) the amount of profit that would have been made." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1329 (Fed. Cir. 2009) (citing *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir.1978)).

Abbott Plaintiffs presented evidence that "but for" Defendants' infringement, Abbott Plaintiffs would have made those sales of Tarka. In fact, Defendants similarly put forth a damages calculation based on every sale of Tarka, thereby seemingly conceding that "but for" its infringement Abbott Plaintiffs would have made those sales. Additionally, Plaintiffs presented evidence as to all four Panduit factors to prove lost profits: significant demand for Tarka, absence of a non-infringing substitute, capacity to meet the demand for Tarka, and lost profits based on

lost sales and price erosion. Defendants argued that the proper measure for damages, if any, was a reasonable royalty based on sales of the generic product. However, the jury, as it was free to do, rejected Defendants' arguments and agreed with Plaintiffs that they were entitled to lost profits damages. This Court finds that there was sufficient evidence for the jury to find that the Abbott Plaintiffs were entitled to lost profits. Accordingly, Defendants' motion is **denied**.

D. OBVIOUSNESS

Defendants move for judgment as a matter of law that the '244 patent is invalid based on obviousness. To prevail on a defense of invalidity for obviousness, Defendants must demonstrate by clear and convincing evidence that:

> the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103(a).

"Patents are presumed to be valid." Proctor & Gamble Co. v. Teva Pharms., 566 F.3d 989, 994 (Fed. Cir. 2009) (citing Kao Corp. v. Unilever United States, Inc., 441 F.3d 963, 968 (Fed. Cir. 2006)). "A party seeking to invalidate a patent based on obviousness must demonstrate 'by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" Id. (citing Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1361 (Fed. Cir. 2007)). "Clear and convincing evidence places in the fact finder 'an abiding conviction that the truth of [the] factual contentions are highly probable.'" Id. (quoting Colorado v. New Mexico, 467 U.S. 310, 316 (1984)).

The Supreme Court has enumerated four factors to be considered by courts to assess whether an invention is obvious. Takeda v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (citing Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966)). The four factors are: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations, or "objective indicia of non-obviousness." Id.; see also KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 405 (2007).

In KSR International Co. v. Teleflex Inc., the Supreme Court cautioned against (1) a rigid application of the teaching, suggestion and motivation ("TSM") test, and (2) a rigid application of using an "obvious to try" analysis when there is pressure to solve a problem with "a finite number of identified, predictable solutions." 127 S. Ct. 1727, 741-42 (2007). Instead, the Court advocated a "common sense" approach to determining obviousness. See id. at 1741-43. Specifically, the Court explained that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining elements in the manner claimed." Id. at 1742. The Court reasoned that, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." Id. at 1740. Even in light of the new approach advocated by KSR, this Court must be cautious to avoid the use of hindsight when considering Defendant's obviousness argument. Thus,

> [i]n conducting an obviousness analysis, [a] factfinder should be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. This is because the genius of invention is often a

combination of known elements that in hindsight seems preordained.

In re Omeprazole Patent Litig., 2007 U.S. Dist. LEXIS 39670, at *400-01 (S.D.N.Y. May 31, 2007) (citation omitted) (quoting KSR, 398 U.S. at 420); see also Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138 (Fed. Cir. 1985).

In the context of chemical compounds, a Defendant challenging the validity of a patent must initially make a prima facie showing of obviousness. Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1345 (Fed. Cir. 2000); Kaufman Co. v. Lantech, Inc., 807 F.2d 970, 974-75 (Fed. Cir. 1986). Such a showing is made under the first Graham factors, as the challenging party must (1) identify the prior art compound that a person of ordinary skill in the art would have chosen as the "lead compound" to select for further research, and (2) show that there is adequate support in the art for making the modifications necessary to arrive at the claimed compounds. Proctor & Gamble Co., 566 F.3d at 994-97; Takeda, 492 F.3d at 1356-57(explaining, after the Supreme Court's decision in KSR, that, "a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound in the prior art," and then the challenging party must identify "a reason that would have prompted a person of ordinary skill in the relevant field to combine [or modify] the elements in the way the claimed new invention does" to prove obviousness.). The "prior art as a whole" must be examined to determine whether a person of ordinary skill in the art would select a compound as a lead, and where there are many potential lead compounds, the selection of one particular compound is not an obvious choice. See Takeda Chemical 492 F.3d at 1363. All relevant properties of the compound must be considered in the obviousness calculus because "[w]hen claimed properties differ from the prior art, those differences, if unexpected and

significant, may lead to nonobviousness." Eli Lilly & Co. v. Zenith Goldline, 471 F.3d 1369, 1378 (Fed. Cir. 2006).

If a party challenging a patent establishes a prima facie case of obviousness, then the patent-holder can rebut this showing by presenting objective evidence of non-obviousness. Yamanouchi, 231 F.3d at 1345. The "objective indicia" of non-obviousness, the fourth Graham factor, instructs courts to consider the circumstances surrounding the invention process including, but not limited to: (1) meeting a long-felt need, (2) the inventors' success despite the failure of others, (3) commercial success, (4) copying, (5) praise and recognition for the invention, (6) unexpected results, and (7) significant effort and serendipity. See Ruiz v. A.B. Chance Co., 234 F.3d 654, 660-62 (Fed. Cir. 2000); see also Proctor & Gamble, 566 F.3d at 994; Ortho-McNeil, 520 F.3d. 1358, 1364 (Fed. Cir. 2002).

Defendants argue that no reasonable jury could find Claim 3 of the '244 patent valid, and that no reasonable jury could find secondary considerations that support non-obviousness. At trial, Defendants presented evidence that pharmaceutical compositions comprising of an ACE inhibitor and a calcium antagonist for the treatment of hypertension were known in the prior art, and that the use of combination drugs for the treatment of hypertension was recommended. Defendants presented evidence that the prior art disclosed numerous combinations of ACE inhibitors and calcium antagonists, and that quinapril was more potent and longer acting than captopril with no clinically significant side effects. Based on the prior art, Defendants argue that the subject matter of Claim 3 is nothing more than a predictable use of prior art elements according to their established functions. Finally, Defendants argue that any evidence as to secondary considerations demonstrating non-obviousness is irrelevant; according to Defendants,

the unexpected benefits are based on comparisons to individual ingredients (rather than combinations) or to a composition that does not represent the closest prior art, and any commercial success enjoyed by Tarka is attributable to marketing and not the merits of the invention.

Plaintiffs argue Defendants failed to meet their burden of proving by clear and convincing evidence that Claim 3 of the '244 patent was obvious. Plaintiffs argue that there was no evidence that combinations of trandolapril and a calcium antagonist, or quinapril and a calcium antagonist, were known at the time of the patent. Additionally, Plaintiffs presented evidence at trial that showed significant differences between the prior art and the claimed subject matter; the prior art taught to combine enalapril and captropril, which are both single ring ACE inhibitors, with the calcium antagonist whereas the claimed subject matter combines double ring ACE inhibitors, trandolapril and quinapril, with a calcium antagonist and this double ring is the key difference. Plaintiffs argue that Defendants failed to show that one of ordinary skill in the art would have been motivated to modify the prior art single ring ACE inhibitor-calcium antagonist combinations to arrive at the claimed double ring ACE inhibitor-calcium antagonist combination. Finally, Plaintiffs presented objective indicia of non-obviousness, such as: the long felt need for an adequate treatment for hypertension and failure of others; the invention's unexpected benefits, including benefits on kidney function, blood vessel improvement, and prevention of diabetes; the invention's commercial success; and Defendants' copying of the invention.

The jury was free to accept, reject, and weigh the evidence presented by both Plaintiffs and Defendants as it deemed fit. The jury found that Defendants did not prove by clear and convincing evidence that Claim 3 of the '244 patent would have been obvious to a person of

ordinary skill in the art, and returned a verdict in favor of Plaintiffs. This Court is unable to conclude that Defendants established their case by evidence the jury would not have been at liberty to disbelieve, or that the only reasonable conclusion based on the evidence presented was that the '244 patent was obvious. In fact, this Court finds that there was sufficient evidence on which the jury could find that '244 patent would not have been obvious to a person of ordinary skill in the art. Accordingly, Defendants' motion for a judgment as a matter of law that the '244 patent is invalid based on obviousness must be **denied**.

E. OBVIOUSNESS TYPE DOUBLE PATENTING

Defendants move for judgment as a matter of law that the '244 patent is invalid based on obviousness type double patenting.

"Patents are presumed to be valid." Proctor & Gamble Co., 566 F.3d at 994 (citing Kao Corp. v. Unilever United States, Inc., 441 F.3d 963, 968 (Fed. Cir. 2006)). A party seeking to invalidate a patent based on obviousness-type double patenting must "prove double patenting by clear and convincing evidence, a heavy and unshifting burden." Symbol Tech., Inc. v. Opticon, Inc., 935 F.2d 1569, 1580 (Fed. Cir. 1991).

"Obviousness-type double patenting is a judicially created doctrine that prevents a patentee from extending the term of a patent by patenting an obvious variation on the original invention." Smith & Nephew, Inc. v. Arthrex, Inc., 2009 U.S. App. LEXIS 26268, *9 (Fed. Cir. Dec. 2, 2009) (citing Georgia-Pacific Corp. U.S. Gypsum Co., 195 F.3d 1322, 1326 (Fed. Cir. 1999)); see also General Foods Corp. v. Studiengesallschaft Kohle mbH, 972 F.2d 1272, 1282 (Fed. Cir. 1992) ("Double patenting is intended to prevent unjustified *extension* of protection."). The purpose of the doctrine of obviousness-type double patenting is to prevent "one person from

obtaining more than one valid patent for either (a) the 'same invention,' or (b) an 'obvious' modification of the same invention." Boehringer Ingelheim Vetmedica, Inc. v. Barr Laboratories, Inc., 592 F.3d 1340, 1346 (Fed. Cir. 2010) (internal citations omitted).

"In general, the obviousness analysis applies to double patenting, except for three distinctions. First, statutory obviousness compares claimed subject matter to the prior art, while non-statutory double patenting compares *claims* in an earlier patent to *claims* in a later patent or application." P&G v. Teva Pharms. USA, Inc., 566 F.3d 989, 998 (2009) (emphasis added). "Second, double patenting does not require inquiry into a motivation to modify the prior art. Finally, double patenting does not require inquiry into objective criteria suggesting non-obviousness." Id. (internal citations omitted).

Under the obviousness-type double patenting doctrine, "a later patent claim is not patentable over an earlier patent claim if the later claim is anticipated by, or obvious in light of, the earlier claim." Smith & Nephew, 2009 U.S. App. LEXIS 26268 at *9 (citing Eli Lilly & Co. v. Barr Labs, Inc., 251 F.3d 955, 968 (Fed. Cir. 2001)). "The law of double patenting is concerned *only* with what patents *claim*... [and] therefore, involves an inquiry into what, if anything has been claimed twice." Id. at 1275. "Obviousness-type double patenting can apply where the earlier patent and later patent are not part of the same patent family and issue from separate parent applications." Otsuka Pharm. Co. V. Sandoz, Inc., No. 07-cv-01000, 2010 WL 4596324, *7 (D.N.J. Nov. 15, 2010). However, when a divisional application results from a restriction requirement in a patent application, there is a safe harbor provision, which provides:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies

> with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. *A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them*, if the divisional application is filed before the issuance of the patent on the other application...

35 U.S.C. § 121 (emphasis added). "When the PTO requires an applicant to withdraw claims to a patentably distinct invention (a restriction requirement), § 121 shields those withdrawn claims in a later divisional application against rejection over a patent that issues from the original application." Boehringer, 592 F.3d at1350 (citing Geneva Pharms., Inc., v. GlaxoSmithKline PLC, 349 F.3d 1373, 1378 (Fed. Cir. 2003). The purpose of the safe harbor provision is to protect an applicant from being penalized for dividing an application. See id. at 1353. In order for the safe harbor provision to apply, two requirements must be met: "only if the divisional application was filed as a result of a restriction requirement and is consonant with that restriction requirement." Bristol-Myers Squibb Co. v. Pharmachemie B.V., 361 F.3d 1343, 1348 (Fed. Cir. 2003).

A "restriction requirement[] must provide a clear demarcation between restricted subject matter to allow determination that claims in continuing applications are consonant and therefore deserving of § 121's protections." Geneva, 349 F.3d at 1381. "To prevent loss of the safe harbor in dividing out claims to non-elected inventions, what is required is consonance with the restriction requirement." Boehringer, 592 F.3d at1350-51. "Consonance requires that the line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as

to bring them back over the line imposed in the restriction requirement. Where that line is crossed the prohibition of the third sentence of Section 121 does not apply." Gerber Garment Tech., Inc. v. Lectra Sys., 916 F.2d 683, 688 (Fed. Cir. 1990). While the claims in the divisional application must be limited to the "non-elected invention or inventions,. [t]he divisions need not be limited to a single one of the examiner's demarcated inventions to preserve the right to rely on the safe harbor of § 121." Boehringer, 592 F.3d at1354 (internal citations omitted).

1. Findings of Fact and Conclusions of Law

Since the jury verdict with regard to obviousness type double patenting was advisory only, this Court "must find the facts specially and state its conclusions of law separately." Fed. R. Civ. P. 52(a). This Court, after weighing the evidence presented at trial and evaluating the credibility of the witnesses, makes the following findings of fact.

This Court finds that the patent examiner issued a restriction requirement on January 5, 1990. The restriction requirement stated that "Claims 1-32 are subject to a restriction or election requirement," and the "application contains claims to more than one synergistic combination of the generic invention." The applicant was directed to choose one invention to pursue in the first patent application. Dr. Becker, the inventor of the subject matter at issue, responded by electing claims 1-5, 8, 13, 17-23, 26-30, and these claims covered ramipril, and similar compounds, in combination with a calcium antagonist. Claims 6, 7, 9-12, 14-16, 24, 25, and 31 were withdrawn from consideration. Therefore, as a result of the restriction requirement and in accordance with PTO's understanding of same, the claims of the '910 patent application were divided into two groups: claims 1-5, 8, 13, 17-23, 30, and 32 were to remain in the '910 patent application, and claims 6, 7, 9-12, 14-16, 24, 25 and 31 were ordered withdrawn and to be pursued, if desired, in a

divisional application.

Withdrawn claims 6 and 24 claim trandolapril in combination with calcium antagonists, and claims 7 and 25 claim quinapril in combination with calcium antagonists. Withdrawn claims 9-12, 14-16, and 31 are generic to trandolapril and quinapril, but are limited to particular calcium antagonists. Withdrawn claims 6 and 7 were combined into Claim 3 of the '244 patent. Although the claims were amended and joined into one claim, the line of demarcation was not crossed; the claims pursued in the divisional application were consonant with the restriction requirement.

Based on the foregoing factual findings, this Court concludes that the safe harbor provision applies. The '244 patent was filed as a result of the restriction requirement, and the '244 maintained consonance with respect to the division of the claims. Therefore, the '910 patent cannot be used as a reference against the '244 patent. Accordingly, Defendants' motion for obviousness type double patenting is **denied**.

III. MOTION FOR PERMANENT INJUNCTION

A. LEGAL STANDARD

In order to obtain a permanent injunction, Plaintiffs "must demonstrate: (1) that [they have] suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between [Plaintiffs] and [Defendants], a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." eBay Inc., et al. v. MercExchange LLC, 547 U.S. 388, 391 (2006).

These principles of equity are well-established, and "apply with equal force to disputes

arising under the Patent Act." Id. The Patent Act provides "courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283; see also eBay, 547 U.S. at 392. There is no general, or categorical, rule that permanent injunctions shall issue once a patent has been adjudged valid and infringed. Id. at 394. "The decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and ... such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." Id. However, "[c]ourts will usually have little trouble making these findings and issuing an injunction in cases between direct competitors." PATENT CASE MANAGEMENT JUDICIAL GUIDE §9.2.1.1 (2009).

B. DISCUSSION

Plaintiffs move for a permanent injunction restraining and enjoining Defendants from selling the generic Tarka product.

1. Irreparable Harm

In determining whether Plaintiffs suffered irreparable harm, this Court may consider "[p]ast harm to the patentee's market share, revenues, and brand recognition" because "[a]lthough injunctions are tools for prospective relief designed to alleviate future harm, by its terms the first eBay factor looks, in part, to what has already occurred." i4i Ltd. Partnership v. Microsoft Corp., 598 F.3d 831, 861-62 (Fed. Cir. 2010). "[L]ost sales standing alone are insufficient to prove irreparable harm" because they are presumed compensable through money damages; but, when viewed in conjunction with other injuries, lost sales can be a factor in the irreparable injury calculation. Automated Merchandising Systems, Inc v. Crane Co., 357 Fed.

Appx. 297, 300-01 (Fed. Cir. 2009). Additionally, lost market share and price erosion can be used to show irreparable harm so long as these claims are substantiated by evidence and not merely speculative. See id.; see also Sanofi-Synthelabo v. Apotex, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (affirming district court's finding of irreparable harm based on price erosion and loss of good will).

Plaintiffs argue that as a result of Defendants' infringing generic Tarka product Plaintiffs have suffered irreparable injuries, such as loss of sales, loss of market share, price erosion, and loss of customer goodwill. Plaintiffs and Defendants are direct competitors in the Tarka market, and prior to Defendants' launch, Plaintiffs had 100% of the Tarka market; now every sale made by Defendants is a sale lost by Plaintiffs. Plaintiffs have lost at least two-thirds of its market share, and expects its market share to decrease further as generic products usually obtain about 90% of the market. Additionally, Plaintiffs have been forced to reduce its prices in order to compete with Defendants' generic product. Plaintiffs argue that they will not be able to regain the price that it once did, and every attempt to increase prices will hurt customer goodwill.

Defendants once again rely on the payment between co-Plaintiffs Sanofi Aventis and Abbott, which, under the 2004 purchasing agreement, Sanofi Aventis was required to pay to Abbott once a generic product achieved a 30% share of the Tarka market, to argue that Abbott did not suffer any harm; instead, according to Defendants, Abbott benefitted as a result of the entry of Glenmark's generic product into the market. As this Court discussed in a prior opinion, and as addressed briefly above, Glenmark cannot rely on this payment to offset the harm caused to Abbott. Moreover, Abbott suffered harm beyond the lost profits resulting from lost sales, including loss of market share, price erosion, and loss of customer goodwill.

Plaintiffs and Glenmark are direct competitors in the Tarka marketplace, and, at trial, Plaintiffs presented evidence demonstrating lost sales, lost market share and price erosion. Accordingly, this Court finds that Plaintiffs have shown that they have suffered irreparable harm, and this factor weighs in favor of a permanent injunction.

2. Inadequate Remedies at Law

An injunction may only issue if Plaintiffs can demonstrate "that remedies available at law, such as monetary damages, are inadequate to compensate for that injury." eBay, 547 U.S. at 391.

Plaintiffs and Defendants are two head-to-head competitors in the Tarka marketplace; every sale of Defendants' generic Tarka is a lost sale by Plaintiffs. As discussed above, Plaintiffs have suffered a loss of market share, harm to reputation, and price erosion, all of which are facts that tend to establish the inadequacy of a legal remedy. See PATENT CASE MANAGEMENT JUDICIAL GUIDE Table 9.1 (2009). Additionally, "a patent holder refusal to grant a license and its engagement in lengthy litigation to protect that business decision," as occurred here, also weighs in favor of finding the remedy at law inadequate. See id. Most importantly, money damages are inadequate because, absent an injunction, Plaintiffs are essentially forced into a compulsory licensing arrangement with a direct competitor, and effectively shut out of enforcing their patent rights. Accordingly, this Court finds that remedies at law are inadequate and this factor weighs in favor of a permanent injunction.

3. Balance of Hardships

The balance of the hardships "assesses the relative effect of granting or denying an injunction on the parties." i4i Ltd. Partnership, 598 F.3d at 862.

Plaintiffs argue that the balance of the hardships weigh in favor of a permanent injunction because it has already suffered, and will continue to suffer, irreparable harm if Defendants are allowed to continue infringing. Plaintiffs spent significant resources in acquiring the patent rights and in developing Tarka's market. Even though it may regain sales once Defendants leave the marketplace, Plaintiffs argue the overall market for Tarka will shrink because patients have become accustomed to paying a lower co-pay for the generic version and will object to an increase. Additionally, even if Defendants exit the market, Plaintiffs argue that they will only be able to regain a fraction of their current market share because it will be difficult to regain its position on the second tier of most managed care organization formularies. Plaintiffs argue that it is suffering irreparable harm due to Defendants' infringing, but, by contrast, any harm Defendants might suffer as a result of an injunction is entirely of their own making. Defendants launched their generic product prior to a final ruling on the validity of the '244 patent, and Plaintiffs argue Defendants should not be permitted to avoid the consequences of this calculated business risk.

Defendants argue that Plaintiffs have failed to prove the balance of hardships favors injunctive relief. First, Defendants argues that they did not disregard Plaintiffs' patent rights when they launched their generic product because they only launched the generic after this Court denied Plaintiffs' motion for a preliminary injunction, and Defendants' executives diligently examined the '244 patent and relied on outside counsel in assisting with Defendants' Paragraph IV patent analysis prior to initiating their product. Additionally, Defendants argue that since Plaintiffs conceded that they will be unable to regain its position on the second tier of most managed care organization formularies, this is a past harm that cannot weigh in favor of an

injunction.

Although Defendants did not launch their generic product until after the preliminary injunction was denied, the preliminary injunction was, by definition, *preliminary* and not a final ruling on the validity of the '244 patent. The fact this Court did not enjoin Defendants from launching their generic product only means that Defendants were not in violation of any court order; it does not negate the fact that in deciding to launch, without a final ruling on the validity of the '244 patent, Defendants undertook a calculated business risk. Any harms Defendants may suffer as a result of an injunction "were almost entirely preventable and were the result of its own calculated risk to launch its product pre-judgment." Sanofi-Synthelabo v. Apotex, 470 F.3d 1368, 1383 (Fed. Cir. 2006). Therefore, this Court finds the balance of the hardships weighs in favor of granting the injunction.

4. Public Interest

"[I]t is generally in the public interest to uphold patent rights." Broadcom Corp. v. Qualcomm Inc., 543 F.3d 683, 704 (Fed. Cir. 2009). Courts "have long acknowledged the importance of the patent system in encouraging innovation. Indeed, the encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude." Sanofi-Synthelabo v. Apotex, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (internal citations omitted). "Importantly, the patent system provides incentive to the innovative drug companies to continue costly development efforts," and therefore there is a "significant public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents." Id. at 1383-84 (internal citations omitted).

Plaintiffs argue that the public interest weighs in favor of enforcing its patent rights.

Pointing to the $290 million dollar payment Abbott made to Sanofi Aventis for exclusive manufacturing rights to Tarka, which included a $151 million dollar payment for the '244 patent with ongoing royalties for sales, Abbott argues that this investment was made with the expectation that the investment could be recouped by selling, to the exclusion of all others, the patented product. Defendants argue that there is a public interest in making lower cost drugs available to consumers, and that if Defendants are enjoined the public will be harmed because they will no longer enjoy the lower cost generic Tarka but rather would be subject to higher prices set through Abbott's monopoly on the market.[2]

Although Defendants raise a legitimate concern, this concern does not outweigh the public interest in protecting and promoting patent rights. "[S]elling a lower priced product does not justify infringing a patent," and although the Hatch-Waxman Act encourages making lower cost generic drugs available to the public, "it does not do so by entirely eliminating the exclusionary rights conveyed by pharmaceutical patents. Nor does the statutory framework encourage or excuse infringement of valid pharmaceutical patents." Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1382 (Fed. Cir. 2005) (internal citations omitted). Abbott invested significant resources with the expectation that it would be able to recoup its investment, and the patent system is designed to provide incentives for innovative drug companies to continue costly development efforts. See Sanofi-Synthelabo, 470 F.3d at 1383. If generic pharmaceutical companies were free to disregard patent rights and simply piggy back off the innovations of others, then the incentives the patent system is designed to promote, namely those that encourage

[2]Glenmark also argues that the public interest disfavors an injunction because the validity of the patent is in significant doubt. As addressed above, the validity of the '244 patent has been resolved and the '244 patent has been found valid both by a jury and by this Court.

continued investment in costly drug development, would disappear. Accordingly, this Court finds that this factor weighs in favor of a permanent injunction.

5. Scope of Permanent Injunction

Based on the foregoing, this Court will grant Plaintiffs' motion for a permanent injunction. The Court must now determine the appropriate scope of the injunction. This Court has broad discretion to tailor an injunction. See Finjan, Inc. V. Secure Computing Corp., 626 F.3d 1197 (Fed. Cir. 2010). However, this Court is mindful that the "injunction, both in scope and effect, [must] strike[] a workable balance between protecting the patentee's rights and protecting the public from the injunction's adverse effects." i4i Ltd. Partnership, 598 F.3d at 863.

a. Generic Tarka

Plaintiffs seek an injunction that prevents Defendants from manufacturing, using, offering to sell, or selling within the United States or importing into the United States generic forms of Tarka. This Court agrees that Defendants' should be so enjoined.

Plaintiffs also argue that, because Defendants sell their products to wholesalers, who then distribute the products to retailers, the injunction should also include a recall of all generic Tarka currently manufactured or distributed so as to prevent further losses to Plaintiffs. See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 106 F. Supp. 2d 696, 710 (D.N.J. 2000).

This Court does not agree that a recall is warranted in this case as the benefit of any recall to Plaintiffs does not outweigh the burden to Defendants, and/or the public. Requiring a recall at the retail level would be onerous and expensive for Defendants, unduly burdensome for the public, and would transform the injunction from prospective into punitive relief. Furthermore,

Plaintiffs have already been awarded damages for bottles sold prior to December 31, 2010, and are entitled to supplemental damages for any bottles sold after that date.

b. Defendants' ANDA

Plaintiffs argue that Defendants should be enjoined from submitting additional ANDAs that are not colorably different from the ANDA for the generic Tarka, from sponsoring another company to submit an ANDA for a generic Tarka, and from manufacturing or selling generic Tarka to another for distribution within the United States. See Abbott Labs. v. Torpharm, Inc., 503 F.3d 1372, 1381 (Fed. Cir. 2007). This Court agrees that Defendants should be so enjoined.

Plaintiffs also argue that this Court must order that the effective date of Defendants' ANDA is the expiration date of the '244 patent pursuant to 35 U.S.C. § 271(e)(4)(A). Section 271(e)(4)(A) provides, that for an act of infringement stemming from the filing of an ANDA, "the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A); see also Ortho-McNeil Pharm., Inc., v. Mylan Labs., Inc., No. 04-cv-1689, 2007 WL 869545, *2 (D.N.J. Mar. 20, 2007). This Court agrees with Defendants that 35 U.S.C. §271(e)(4)(A) is inapplicable to this case because the infringing acts fall under 35 U.S.C. § 271(a) (direct infringement), § 271(b) (inducement), and § 271(c) (contributory infringement), not under §271(e)(4)(A) (infringement based on the act of filing the ANDA). Accordingly, this Court will deny Plaintiffs' request for an order changing the ANDA effective date.

6. Accounting for Supplemental Damages

Plaintiffs seek supplemental damages for Defendants' infringing sales that were not

included within the jury's award of damages. The damages evidence presented at trial was limited to the calculation of damages through December 31, 2010. However, Defendants have continued to sell their generic Tarka product. Accordingly, this Court agrees that Plaintiffs are entitled to an accounting of the generic products sold by Defendants so that supplemental damages can be calculated. The parties agree that, based on the jury award of lost profits, the calculation of supplemental damages is $154.10 per bottle. Defendants have 30 days from the entry of this Opinion and Order to provide the total number of bottles sold from January 1, 2011. At that time, this Court will address whether there should be supplemental damages with regard to price erosion, any prejudgment interest and what rate, i.e. the prime rate or treasury bill rate, will be used.

IV. CONCLUSION

For the foregoing reasons, Defendants' motions for judgment as a matter of law with regard to standing, lost profits, obviousness and obviousness type double patenting are **denied**; Abbott Plaintiff's motion for a permanent injunction is **granted**; and Abbott Plaintiff's motion for supplemental accounting of damages is **granted**.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Dated: September 30, 2011
cc: All Counsel of Record
Hon. J. A. Dickson, U.S.M.J.
File